

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on March 16, 2005, and the references cited therewith.

Claims 1, 7 and 20 are amended, claims 33-40 are withdrawn, and claims 1-40 are now pending in this application.

Affirmation of Election

Restriction to one of the following claims was required: Group I (claims 1-32) drawn to a method of analyzing a sample, and Group II (claims 33-40) drawn to a microsphere comprising of an organic solvent soluble hydrophobic electroactive marker. As provisionally elected with traverse by Applicant's representative, Steve Slusher, on March 2, 2005, Applicant elects to prosecute the invention of Group I, claims 1-32. Restriction between the claims is improper because the process cannot be practiced with another materially different product such as colorimetric particles or a solid phase incorporated with a fluorescence dye since the signal from those other products is not distinguishable one from the other if the sample contains a heterogenous population of colorimetric particles or fluorescent dyes. This is in contrast to the electroactive microspheres and the method of detecting the same since a heterogenous population of beads, each population having a characteristic electrochemical fingerprint would provide a signal that is informative as to the ratio of each population of microsphere in the sample. See Applicant's specification at page 14, lines 5-20. Further, electroactive microparticles allow for detection of binding pairs at concentrations below the detectable limits for the signals generated by colorimetric particles and fluorescent dyes. See Applicant's specification at page 5, lines 10-12 and page 18 lines 11-24. Therefore, restriction is not proper. However, Applicant reserves the right to later file continuations or divisions having claims directed to the non-elected inventions.

Double Patenting Rejection

Claims 1, 10, 11, 15, 20, 24, 28 were rejected under the judicially created doctrine of double patenting over claims 1, 2, 3, 7, 8, 73, 74 of Application No.10/796,765.

A Terminal Disclaimer in compliance with 37 CFR 1.321(b)(iv) is enclosed herewith to overcome these rejections.

'112 Rejection of the Claims

Claims 1-32 were rejected under 35 USC ' 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner rejects claim 1 for omitting steps such as introducing the microspheres incorporating a member of the specific binding pair; introducing the sample containing the partner that

forms a complex with the member of the specific binding pair incorporated therein; and correlating detecting the presence of the specific binding pair.

Claim 1 is currently amended to recite steps suggested by the Examiner. Applicant believes that amended claim 1 complies with MPEP 2177.01 and overcomes the Examiner's rejection.

The Examiner rejects claim 10 for failing to recite what is to be incubated in the incubation step.

Claim 10 is currently amended to further clarify what is to be incubated.

The Examiner rejects claim 20 for failing to recite a correlation step of analyzing the sample for the presence of two or more analytes as recited in the preamble of the claim.

Claim 20 is currently amended to recite a detection step.

'102 Rejection of the Claims

Claims 1, 2, 4, 5, 7, 8, 10-13, 17-19 were rejected under 35 USC ' 102(b) as being anticipated by Durst et al. (U.S.5,789,154). Durst teaches a solid phase method of detecting binding pairs wherein a liposome encapsulating electroactive particles supports at least one of the two elements of the binding pair. Durst is limited to liposomes carrying electroactive particles and detection of the electroactive particles on a solid phase support after lysing the liposome to release the electroactive particles. See '154 at column 5, lines 22-34.

Independent claim 1 is currently amended to exclude liposome as a microsphere. Applicant's specification expressly teaches the limitations of the use of liposomes and the limitation of using the same. See Applicant's specification at page 2 lines 17-21. Therefore, claim 1 is patentable over Durst.

Claims 2, 4, 5, 7, 8, 10-13 and 17-19 depend from claim 1 and are patentable for at least the reasons cited in claim 1.

Claims 1, 2, 4, 5, 10-13, 16-21, 24-26, 29-32 were rejected under 35 USC ' 102(e) as being anticipated by Lu et al. (U.S.6,485,983). Lu teaches a solid phase analyte detection system which requires the labeling of a least one of the members of the binding pair with an electroactive particle. The detection requires a two step method of detection of the electrochemical labeled ligand wherein first the label is removed from the immobilized ligand after which the label is reduced. The reduced electrochemical fingerprint is monitored as a reporter of the concentration of the ligand immobilized. See '983 at column 5, lines 36-43.

Independent claim 1 is patentable over Lu since the electroactive particles incorporated into each microsphere provide a characteristic fingerprint to the microsphere and do not modify the ligand, no solid phase support is required for detection and the electrochemical fingerprint of the microsphere is detectable immediately without further modification.

Claims 2, 4, 5, 10-13, 16-21, 24-26, 29-32 depend from claim 1 and are patentable for at least the reasons cited in claim 1.

Claims 1- 4, 6-11, 14, 15, 20-24, 27, 29, and 30 were rejected under 35 USC ' 102(e) as being anticipated by Bamdad (U.S.2003/0059955). Bamdad discloses a method of detection of a nanoparticle

supporting a specific binding pair wherein the method of detection is via fluorescence, or emission of light such as visible light, infrared light, ultraviolet light or radio frequency radiation. See Bamdad at paragraphs 53-57 at pages 5-6. Bamdad does not teach voltammetric detection of an electroactive that is integrated into the nanoparticle and is detected via voltammetry thereby resulting in a unique fingerprint generated for each class of electroactive nanoparticles. No where does Bamdad teach or suggest electrochemical detection of the "electroactive nanoparticle". See Bamdad, paragraph 75; see also Bamdad, paragraph 45.

Independent claim 1 is patentable over Bamdad since Bamdad does not teach detection of microsphere with electrochemical detection. Applicant's specification at page 11, line 25 through page 12, line 7 defines electrochemical detection as "'Electrochemical detection" includes the measurement of one or more electrical quantities, such as current, potential or charge, in relationship to one or more chemical parameters. For the present invention, stripping voltammetry is one preferred method for the electrochemical detection of nanocrystals such as CdS, ZnS, or PbS. However, other methods and means of electrochemical detection (e.g., chronopotentiometric measurements, such as chronopotentiometric detection) can be employed provided that such methods or means permit detection of the electroactive marker. With regard to stripping voltammetry, any of a variety of waveforms can be employed, including square wave stripping voltammetry, linear sweep stripping voltammetry, anodic stripping voltammetry, differential pulse cathodic stripping voltammetry, and square wave adsorptive stripping voltammetry. Electrodes, methods of detection and analysis, and the like are generally disclosed in Analytical Electrochemistry by Joseph Wang, VCH Publishers, Inc., New York, 1994, incorporated herein by reference."

In contrast, Bamdad uses an art conventional method for detection, and in no way teaches detection of the nanoparticle itself by electrochemical detection. Therefore, independent claim 1 and claims depending therefrom (2-10, and 73-75) are patentable over Bamdad.

Claims 1, 2, 4, 7, 10-12, 17, 18-19 were rejected under 35 USC ' 102(e) as being anticipated by Knoll (U.S.6,548,311). Knoll teaches a detection method that is purely electrical in nature wherein particles bond to a substrate lead to a modification of an electrical signal which is based upon field effect induced by marker particles such as beads with no electroactive markers associated therewith. See '311 at column 9, lines 26-29. The marker particles are electrically insulating in a solution, induced by electrodes, to have an electric field and electric current. The signal is dependent upon bound marker particles which disturb or change the electrical resistance between a first electrode at the surface of the substrate of which marker particles are bound and a counter-electrode. Knoll does not teach a microsphere with an electroactive marker associated therewith to induce a characteristic electrical fingerprint that is unique to each electroactive marker.

Independent claim 1 is patentable over Knoll since Knoll does not teach detecting the specific binding pair complex by electrochemical testing for the electroactive marker.

Claims 2, 4, 7, 10-12, 17, 18-19 depend from claim 1 and are patentable for at least the reasons as cited in support of claim 1.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (505 998 1501) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-4213

Respectfully submitted,

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Date June 29, 2005

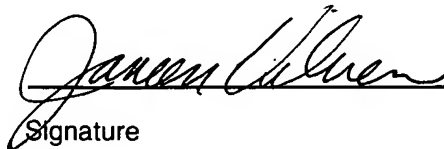
By


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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of June, 2005.

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